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(54) **BLOOD COLLECTION TUBE HOLDER WITH SINGLE NEEDLE**

HALTER FÜR BLUTSAMMELRÖHRCHEN MIT EINZELNADEL

SUPPORT DE TUBE DE PRÉLÈVEMENT SANGUIN À AIGUILLE UNIQUE

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Description

1. Field of the Invention

[0001] The present invention relates to a blood collection tube holder. This invention is a medical device useful for drawing blood from person or animal. The subject device is often referred to as a "blood collection tube holder" or "blood tube holder." because it is configured for use in combination with conventional, commercially available "blood collection tubes" or "blood tubes" that are manufactured and marketed by several different companies. The invention also relates to a single use blood collection tube holder having a single needle that is retractable into a confined space inside the device following use to protect a patient and healthcare workers from accidental needle sticks and thereby reduce the associated likelihood of pathogenic contamination resulting from an accidental stick. One aspect of the invention relates to a blood collection tube holder having a body comprising substantially parallel and laterally spaced apart barrel and needle retraction cavities separated by a partial wall that facilitates lateral movement of a retractable single needle from the barrel cavity into alignment with the needle retraction cavity to initiate needle retraction. Another aspect of the invention relates to a blood collection tube holder having a barrel and a frontal attachment that are cooperatively configured to facilitate relative sliding movement between them in a direction that is transverse to the longitudinal axis through the needle.

2. Description of Related Art

[0002] Conventional blood collection tube holders are disclosed, for example, in United States Patent Nos. 5,810,775; RE39,107; 8,496,600; 9,247,899 and in United States Publication Nos. 20160310057; 20180008180 and 2018/0008181.

[0003] Some such devices have two separate needles including a venipuncture needle pointing forwardly and a discharge needle pointing rearwardly. The discharge needle penetrates a stopper disposed in the front of a blood collection tube when the tube is inserted into the open rear end of a barrel. Following collection of a fluid sample, the blood collection tube is removed from the barrel of the blood tube holder, and a polymeric sheath expands to cover the rearwardly facing needle tip to prevent bodily fluid from leaking out the open back of the barrel. In one such device, a hinged cap is provided at the back of the barrel, and closing the cap following removal of the blood collection tube triggers retraction of both the discharge needle and the venipuncture needle rearwardly into the barrel, whereby the device is rendered "safe" and non-reusable.

[0004] More recently, blood collection tube holders have been disclosed that comprise a longer, rearwardly biased single needle having both forwardly and rearwardly facing pointed ends. Following collection of a fluid sam-

ple and removal of the blood collection tube, needle retraction is initiated by depressing an actuator containing a needle retraction cavity that is moved to a position where it is sufficiently aligned with the needle that both ends of the needle are biased backwardly into the needle retraction cavity of the device, whereby the device is rendered "safe" and non-reusable.

[0005] Even more recently, blood collection tube holders have been disclosed that comprise separate venipuncture and discharge needles, and a retraction cavity for the venipuncture needle that is disposed beside and parallel to the barrel, either as a separate chamber that is made integrally with the barrel or as part of a frontal attachment to the barrel. The venipuncture needle is rearwardly biased and retraction of the venipuncture needle is initiated by transverse sliding movement of at least part of the frontal attachment to the barrel. During such movement the forwardly projecting venipuncture needle is moved laterally out of alignment with the rearwardly facing discharge needle into substantially coaxial alignment with the needle retraction cavity. Once the venipuncture needle is substantially aligned with the needle retraction cavity, the rearwardly directed biasing force causes the venipuncture needle to be withdrawn to a "safe" position inside the device while the discharge needle remains disposed in its original position inside the barrel. Either before or after needle retraction, the blood collection tube can be removed from the barrel, and an elastomeric sheath expands over the rearwardly facing tip of the discharge needle to prevent bodily fluid from leaking out the open rear end of the barrel.

[0006] Notwithstanding the improvements and advantages achieved through use of the previously disclosed devices, a blood collection tube hold is needed that comprises a single needle which can be retracted following use by lateral sliding movement of a frontal attachment relative to the barrel to reposition the whole needle into substantially coaxial alignment with a full-length needle retraction cavity that is made integrally with the barrel. Further relevant prior art is described in WO2018009329, US2014276435, US 2015 / 073304 A1, and US 5 052 403 A. WO 2018009329 describes a blood collection tube holder comprising a substantially cylindrical body comprising a barrel and a needle retraction cavity; a frontal attachment; and a retractable needle comprising a venipuncture end; wherein the body and the frontal attachment are cooperatively configured to facilitate sliding lateral movement of the body relative to the retractable needle prior to needle retraction.

SUMMARY OF THE INVENTION

[0007] In order to solve the aforementioned problem, it is provided a blood collection tube holder having the features defined in claim 1. Further preferred embodiments are defined in the dependent claims.

[0008] The venipuncture end of the single needle projects forwardly from the frontal attachment and is de-

sirably covered by a selectively releasable needle cap prior to use. The frontal attachment further comprises a tube holder connector that frictionally engages and partially covers the open front end of the barrel, and a slide member that slidably engages the tube holder connector along an axis that is substantially transverse to the longitudinal axis through the single needle. The slide member is configured to seat and support a rearwardly biased needle holder attached in fixed relation to the single needle. The tube holder connector further comprises a transverse slot that facilitates relative lateral movement of the single needle between the first and second positions when oppositely directed manual pressure is applied to the body and slide member for the purpose of substantially aligning the needle holder and needle retraction cavity to initiate retraction of the single needle into the needle retraction cavity. In one preferred embodiment of the invention, the selectively releasable needle cap further comprises a locking arm that prevents the slide member and the needle retraction cavity from becoming substantially aligned and thereby initiating retraction of the single needle prior to use.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The apparatus of the invention is further described and explained in relation to the following drawings wherein:

FIG. 1 is a front perspective view of one embodiment of the blood collection tube holder of the invention; FIG. 2 is a front perspective view of the blood collection tube holder of FIG. 1 with the needle cap removed; FIG. 3 is a rear perspective view of the blood collection tube holder of FIG. 1; FIG. 4 is a top plan view of a blood collection tube holder substantially as shown in FIGS. 1 and 3 except that indicia are also shown in dashed outline in FIG. 4; FIG. 5 is a front view of the blood collection tube holder of FIG. 1 but rotated 90 degrees in a clockwise direction around its longitudinal axis; FIG. 6 is a rear view of the blood collection tube holder of FIG. 5; FIG. 7 is a top plan view of the blood collection tube holder of FIG. 4 with the needle cap removed; FIG. 8 is a right side elevation view of the blood collection tube holder of FIGS. 1 and 3; FIG. 9 is a left side elevation view of the blood collection tube holder of FIG. 1 rotated 180 degrees in a clockwise direction around its longitudinal axis; FIG. 10 is a cross-sectional view taken along line A-A of FIG. 5; FIG. 11 is an exploded perspective view of the blood collection tube holder of FIG. 1; FIG. 12 is the blood collection tube holder of FIG. 7 with the venipuncture needle retracted;

FIG. 13 is the blood collection tube holder of FIG. 5 with the needle cover removed and the venipuncture needle retracted;

FIG. 14 is a cross-sectional view taken along line C-C or FIG. 13;

FIG. 15 is the blood collection tube holder of FIG. 2 with the needle retracted;

FIG. 16 is an enlarged detail view of the needle support member of FIG. 11;

FIG. 17 is a rear perspective view of the needle support member of FIG. 16 rotated 180 degrees in a clockwise direction around the longitudinal axis through the subject blood collection tube holder;

FIG. 18 is an enlarged detail view of the tube holder connector of FIG. 11;

FIG. 19 is a rear perspective view of the tube holder connector of FIG. 18 rotated 180 degrees in a clockwise direction around the longitudinal axis through the subject blood collection tube holder; and

FIG. 20 is an enlarged cross-sectional view taken along line B-B of FIG. 4.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0010] Referring to FIGS. 1-11, blood collection tube holder 10 comprises body 12, a frontal attachment further comprising tube holder connector 24 and slide member 38, needle cap 40 (FIGS. 1 and 3), and retractable single needle 30 (FIG. 2). Body 12 further comprises barrel 16, barrel cavity 14, needle retraction chamber 20 and rear flange 22 disposed around the rear opening of barrel 16. Referring to FIGS. 2 and 7, retractable single needle 30 projects forwardly from needle support member 46 of slide member 38 of the frontal attachment.

[0011] Referring to FIGS. 4-6 and 8-10, blood collection tube holder 10 is depicted in its pre-use position in which selectively removable needle cap 40 is installed over retractable single needle 30 and frictionally engages axially extending, circumferentially spaced ribs disposed around needle support member 46 (visible in FIG. 7). Locking support arm 42 (visible in FIGS. 10-11) is provided to prevent relative sliding movement between body 12 and slide member 38 prior to using retractable single needle 30 to draw blood from a patient. Slide member 38 further comprises front surface 44 from which needle support member 46 projects forwardly around part of retractable single needle 30 as best seen in FIG. 7.

[0012] Referring to FIGS. 10-11, retractable single needle 30 further comprises forwardly facing venipuncture end 32 and rearwardly facing fluid discharge end 34. Prior to insertion of a blood collection tube (not shown) into barrel cavity 14 and use of blood collection tube holder 10 for collecting blood from a patient, selectively releasable needle cap 40 is in place as discussed above, and collapsible elastomeric sheath 26 covers fluid discharge end 34 of retractable single needle 30 to shield fluid discharge end 34 from inadvertent contamination. When a blood collection tube is inserted into barrel cavity

14 of barrel 16 of body 12, sheath 26 is collapsed rearwardly around retractable single needle 30, allowing fluid discharge end 34 to penetrate an elastomeric stopper in the blood collection tube to establish fluid communication between venipuncture end 32 of retractable single needle 30 and the inside of the blood collection tube into which the drawn blood is discharged. When single retractable needle 30 is in its pre-use position as shown in FIG. 10, needle 30 is substantially centered inside barrel cavity 14 and is laterally spaced apart from needle retraction cavity 76 inside needle retraction chamber 20 of body 12.

[0013] Referring again to FIGS. 10-11, retractable single needle 30 is desirably attached in fixed axial relation to needle holder 28, 92, which further comprises a rearwardly extending annular projection 94 provided for use in frictionally engaging the forwardly extending end of collapsible elastomeric sheath 26, which is preferably a rubber sleeve. A biasing member such as compressible coiled spring 36 is desirably seated inside bore 60 (FIG. 16) of needle support member 46 around a centrally disposed portion of needle 30 and the forwardly facing shaft portion of needle holder 26, and when compressed during assembly of blood collection tube holder 10, abuts and engages the front side of head 92 of needle holder 28. For so long as retractable single needle 30 remains in its forwardly projecting position, head 92 of needle holder 28 is biased rearwardly relative to the frontal attachment and body 12 of blood collection tube holder 10.

[0014] Referring to FIGS. 11, 16-17 and 20, slide member 38 of the frontal attachment to body 12 (FIG. 7) further comprises opposed positioning blocks 54, 56 that are engageable with cooperatively configured head 92 of needle holder 28 (FIG. 11) to move needle holder 28 laterally as discussed below. Laterally extending top and bottom rails 50, 52, respectively, are cooperatively configured and slidably engageable with laterally extending top and bottom rails 68, 70 of tube holder connector 24. Referring to FIGS. 17-18, projections 96, 98 (FIG. 17) on slide member 38 are desirably provided to engage cooperatively configured and aligned recesses 100 (bottom recess not visible) of tube holder connector 24 to properly position retractable single needle 30 within slot 72 of tube holder connector 24 during assembly and use of blood collection tube holder 10. Referring to FIGS. 11, 18-19, circumferentially extending arcuate ring 64 and cooperating circular wall 62 of tube holder connector 24 are provided to establish frictional engagement between tube holder connector 24 and the forwardly facing edge of barrel 16 of body 12. The frictional engagement is desirably sufficient that tube holder connector 24 remains attached to the front end of barrel 16 as oppositely directed pressure is applied to textured touch surfaces 74, 48 as discussed below.

[0015] FIGS. 5-6 and 13 further depict opposed flat edges 84, 86 in relation to opposed arcuate edges 88, 90 of flange 22 and the relative positions of slide member 38 and tube holder connector 24 whenever needle 30 is in the unretracted and retracted positions, respectively.

[0016] Referring to FIGS. 5 and 7-11, slide member 38 and tube holder connector 24 of the frontal attachment to body 12 are provided with textured touch pads 48, 74, respectively, to facilitate the application of oppositely directed manual pressure to each touch pad to produce lateral sliding movement of body 12 relative to slide member 34, needle holder 28, compression spring 36 and retractable single needle 30. This movement is desirably in a transverse direction that causes discharge needle end 34 of retractable single needle 30 to move laterally past reduced height portion 80 of partial wall 82 (FIG. 10) until needle 30 is substantially aligned with needle retraction cavity 76, which allows needle holder 28 and discharge needle end 34 to move rearwardly into needle retraction cavity 76 as compressed coil spring 36 expands to the position shown in FIG. 14. The length of retractable single needle 30 is desirably such that venipuncture end 32 of needle 30 is fully contained inside needle support member 46 of slide member 38 when in the position as shown in FIG. 14. FIGS. 12-15 depict blood collection tube holder 10 of the invention with retractable single needle 30 in the fully retracted position.

Claims

1. A blood collection tube holder (10) comprising:

a substantially cylindrical body (12) comprising a barrel (16) and a needle retraction cavity (20); a frontal attachment (24, 38); and a retractable single needle (30) comprising a venipuncture end (32) and a fluid discharge end (34) that are oppositely directed; wherein the body (12) and the frontal attachment (24, 38) are cooperatively configured to facilitate sliding lateral movement of the body (12) relative to the retractable single needle (30) prior to needle retraction, wherein the fluid discharge end (34) is configured to penetrate an elastomeric stopper in a blood collection tube being inserted into a barrel cavity (14) of the barrel (16) for collecting blood of a patient in order to establish a fluid communication between the venipuncture end (32) and an inside of the blood collection tube, wherein the body (12) further comprises the barrel cavity (14) which is substantially cylindrically and wherein the needle retraction cavity (20) is integrally formed, wherein the barrel cavity (14) and the needle retraction cavity (20) are substantially parallel and separated by a partial wall (80), wherein the partial wall (80) is configured to facilitate sliding lateral movement of the fluid discharge end (34) of the retractable single needle (30) from a first position where retractable single needle (30) is substantially centered inside of and coaxially aligned with the barrel cavity (14) to a second position where the

retractable single needle (30) is substantially aligned with the needle retraction cavity (20).

2. The blood collection tube holder (10) of claim 1 wherein the venipuncture end (32) of the retractable single needle (30) projects forwardly from the frontal attachment (24, 38). 5
3. The blood collection tube holder (10) of claim 1 wherein the venipuncture end (32) of the retractable single needle (30) is covered by a selectively releasable needle cap (40) prior to use. 10
4. The blood collection tube holder (10) of claim 1 wherein the frontal attachment (24, 38) further comprises a slide member (38) and a tube holder connector (24). 15
5. The blood collection tube holder (10) of claim 4 wherein the tube holder connector (24) engages and partially covers the open front end of the barrel (16). 20
6. The blood collection tube holder (10) of claim 5 wherein the slide member (38) slidably engages the tube holder connector (24) along an axis that is substantially transverse to a longitudinal axis through the retractable single needle (30). 25
7. The blood collection tube holder (10) of claim 1 wherein the slide member (38) is configured to seat and support a rearwardly biased needle holder attached in fixed relation to the retractable single needle (30). 30
8. The blood collection tube holder (10) of claim 1 wherein the tube holder connector (24) further comprises a transverse slot that facilitates relative lateral movement of the retractable single needle (30) between the first and second positions when oppositely directed manual pressure is applied to the body and to the slide member (38). 35
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9. The blood collection tube holder (10) of claim 3 wherein the selectively releasable needle cap (40) further comprises a locking arm that prevents the slide member (38) and the needle retraction cavity (20) from becoming substantially aligned prematurely and thereby initiating needle retraction prior to use of the blood collection tube holder for drawing blood. 45

Patentansprüche

1. Blutsammelröhrchenhalter (10), umfassend:
einen im Wesentlichen zylindrischen Körper (12), der einen Zylinder (16) und einen Hohlraum zum Zurückziehen der Nadel (20) umfasst;

eine vordere Befestigung (24, 38); und eine einziehbare einzelne Nadel (30), die ein Venenpunktionsende (32) und ein Flüssigkeitsabgabeende (34) aufweist, die entgegengesetzt gerichtet sind;
wobei der Körper (12) und die vordere Befestigung (24, 38) zusammenwirkend konfiguriert sind, um eine gleitende seitliche Bewegung des Körpers (12) relativ zu der zurückziehbaren einzelnen Nadel (30) vor dem Zurückziehen der Nadel zu erleichtern, wobei das Flüssigkeitsabgabeende (34) so konfiguriert ist, dass es einen elastomeren Stopfen in einem Blutsammelröhrchen durchdringt, das in einen Zylinderhohlraum (14) des Zylinders (16) zum Sammeln von Blut eines Patienten eingeführt wird, um eine Flüssigkeitsverbindung zwischen dem Venenpunktionsende (32) und einer Innenseite des Blutsammelröhrchens herzustellen, wobei der Körper (12) ferner den Zylinderhohlraum (14) umfasst, der im Wesentlichen zylindrisch ist, und wobei der Nadelrückzugshohlraum (20) einstückig ausgebildet ist, wobei der Zylinderhohlraum (14) und der Nadelrückzugshohlraum (20) im Wesentlichen parallel und durch eine Teilwand (80) getrennt sind, wobei die Teilwand (80) so konfiguriert ist, dass sie eine gleitende seitliche Bewegung des Flüssigkeitsabgabeendes (34) der zurückziehbaren einzelnen Nadel (30) von einer ersten Position, in der die zurückziehbare einzelne Nadel (30) im Wesentlichen innerhalb des Zylinderhohlraums (14) zentriert und koaxial mit diesem ausgerichtet ist, in eine zweite Position, in der die zurückziehbare einzelne Nadel (30) im Wesentlichen mit dem Nadelrückzugshohlraum (20) ausgerichtet ist, erleichtert.

2. Blutsammelröhrchenhalter (10) nach Anspruch 1, wobei das Venenpunktionsende (32) der einziehbaren einzelnen Nadel (30) von der vorderen Befestigung (24, 38) nach vorne vorsteht.
3. Blutsammelröhrchenhalter (10) nach Anspruch 1, wobei das Venenpunktionsende (32) der einziehbaren einzelnen Nadel (30) vor der Verwendung durch eine selektiv lösbare Nadelkappe (40) abgedeckt wird.
4. Blutsammelröhrchenhalter (10) nach Anspruch 1, wobei die vordere Befestigung (24, 38) ferner ein Gleitelement (38) und einen Röhrchenhalteranschluss (24) umfasst.
5. Blutsammelröhrchenhalter (10) nach Anspruch 4, wobei der Röhrchenhalteranschluss (24) in das offene vordere Ende des Zylinders (16) eingreift und dieses teilweise abdeckt.

6. Blutsammelröhrchenhalter (10) nach Anspruch 5, wobei das Gleitelement (38) entlang einer Achse, die im Wesentlichen quer zu einer Längsachse durch die einziehbare einzelne Nadel (30) verläuft, gleitend mit dem Röhrchenhalteranschluss (24) in Eingriff steht. 5
7. Blutsammelröhrchenhalter (10) nach Anspruch 1, wobei das Gleitelement (38) so konfiguriert ist, dass es einen nach hinten vorgespannten Nadelhalter, der in fester Beziehung zu der einziehbaren einzelnen Nadel (30) angebracht ist, aufnimmt und trägt. 10
8. Blutsammelröhrchenhalter (10) nach Anspruch 1, wobei der Röhrchenhalteranschluss (24) ferner einen Querschlitz aufweist, der eine relative seitliche Bewegung der einziehbaren einzelnen Nadel (30) zwischen der ersten und der zweiten Position erleichtert, wenn ein entgegengesetzt gerichteter manueller Druck auf den Körper und auf das Gleitelement (38) ausgeübt wird. 15 20
9. Blutsammelröhrchenhalter (10) nach Anspruch 3, wobei die selektiv lösbare Nadelkappe (40) ferner einen Verriegelungsarm umfasst, der verhindert, dass das Gleitelement (38) und der Nadelrückzugshohlraum (20) vorzeitig im Wesentlichen ausgerichtet werden und dadurch der Nadelrückzug vor der Verwendung des Blutsammelröhrchenhalters zur Blutentnahme eingeleitet wird. 25 30

Revendications

1. Support de tube de prélèvement de sang (10) comprenant : 35

un corps (12) sensiblement cylindrique comprenant un cylindre (16) et une cavité de rétraction d'aiguille (20) ; une fixation frontale (24, 38) ; et 40

une aiguille rétractable unique (30) comprenant une extrémité de ponction veineuse (32) et une extrémité d'évacuation de fluide (34) qui sont orientées de manière opposée ;

le corps (12) et la fixation frontale (24, 38) étant configurés de manière à coopérer pour faciliter un mouvement latéral de coulissement du corps (12) par rapport à l'aiguille rétractable unique (30) avant la rétraction d'aiguille, l'extrémité d'évacuation de fluide (34) étant configurée pour 50

pénétrer dans un bouchon élastomère dans un tube de prélèvement de sang qui est inséré dans une cavité de cylindre (14) du cylindre (16) pour prélever le sang d'un patient afin d'établir une communication fluide entre l'extrémité de ponction veineuse (32) et un intérieur du tube de prélèvement de sang, le corps (12) comprenant en outre la cavité de cylindre (14) qui est 55

- sensiblement cylindrique et dans laquelle la cavité de rétraction d'aiguille (20) est formée de manière solidaire, la cavité de cylindre (14) et la cavité de rétraction d'aiguille (20) étant sensiblement parallèles et séparées d'une paroi partielle (80), la paroi partielle (80) étant configurée pour faciliter un mouvement latéral de coulissement de l'extrémité d'évacuation de fluide (34) de l'aiguille rétractable unique (30) depuis une première position où l'aiguille rétractable unique (30) est sensiblement centrée à l'intérieur de, et alignée coaxialement avec, la cavité de cylindre (14) vers une seconde position où l'aiguille rétractable unique (30) est sensiblement alignée sur la cavité de rétraction d'aiguille (20).
2. Support de tube de prélèvement de sang (10) selon la revendication 1, l'extrémité de ponction veineuse (32) de l'aiguille rétractable unique (30) se projetant vers l'avant depuis la fixation frontale (24, 38).
 3. Support de tube de prélèvement de sang (10) selon la revendication 1, l'extrémité de ponction veineuse (32) de l'aiguille rétractable unique (30) étant recouverte d'un capuchon d'aiguille sélectivement détachable (40) avant l'utilisation.
 4. Support de tube de prélèvement de sang (10) selon la revendication 1, la fixation frontale (24, 38) comprenant en outre un élément coulissant (38) et un connecteur de support de tube (24).
 5. Support de tube de prélèvement de sang (10) selon la revendication 4, le connecteur de support de tube (24) engageant et recouvrant partiellement l'extrémité avant ouverte du cylindre (16).
 6. Support de tube de prélèvement de sang (10) selon la revendication 5, l'élément coulissant (38) engageant de manière à pouvoir coulisser le connecteur de support de tube (24) le long d'un axe qui est sensiblement transversal à un axe longitudinal à travers l'aiguille rétractable unique (30).
 7. Support de tube de prélèvement de sang (10) selon la revendication 1, l'élément coulissant (38) étant configuré pour loger et supporter un support d'aiguille sollicité vers l'arrière fixé, en relation fixe, à l'aiguille rétractable unique (30).
 8. Support de tube de prélèvement de sang (10) selon la revendication 1, le connecteur de support de tube (24) comprenant en outre une fente transversale qui facilite un mouvement latéral relatif de l'aiguille rétractable unique (30) entre la première et la seconde position lorsqu'une pression manuelle dirigée de manière opposée est appliquée au corps et à l'élément coulissant (38).

9. Support de tube de prélèvement de sang (10) selon la revendication 3, le capuchon d'aiguille sélectivement détachable (40) comprenant en outre un bras de verrouillage qui empêche l'élément coulissant (38) et la cavité de rétractation d'aiguille (20) de se retrouver sensiblement alignés prématurément et d'initier ainsi une rétractation d'aiguille avant l'utilisation du support de tube de prélèvement de sang pour extraire du sang.

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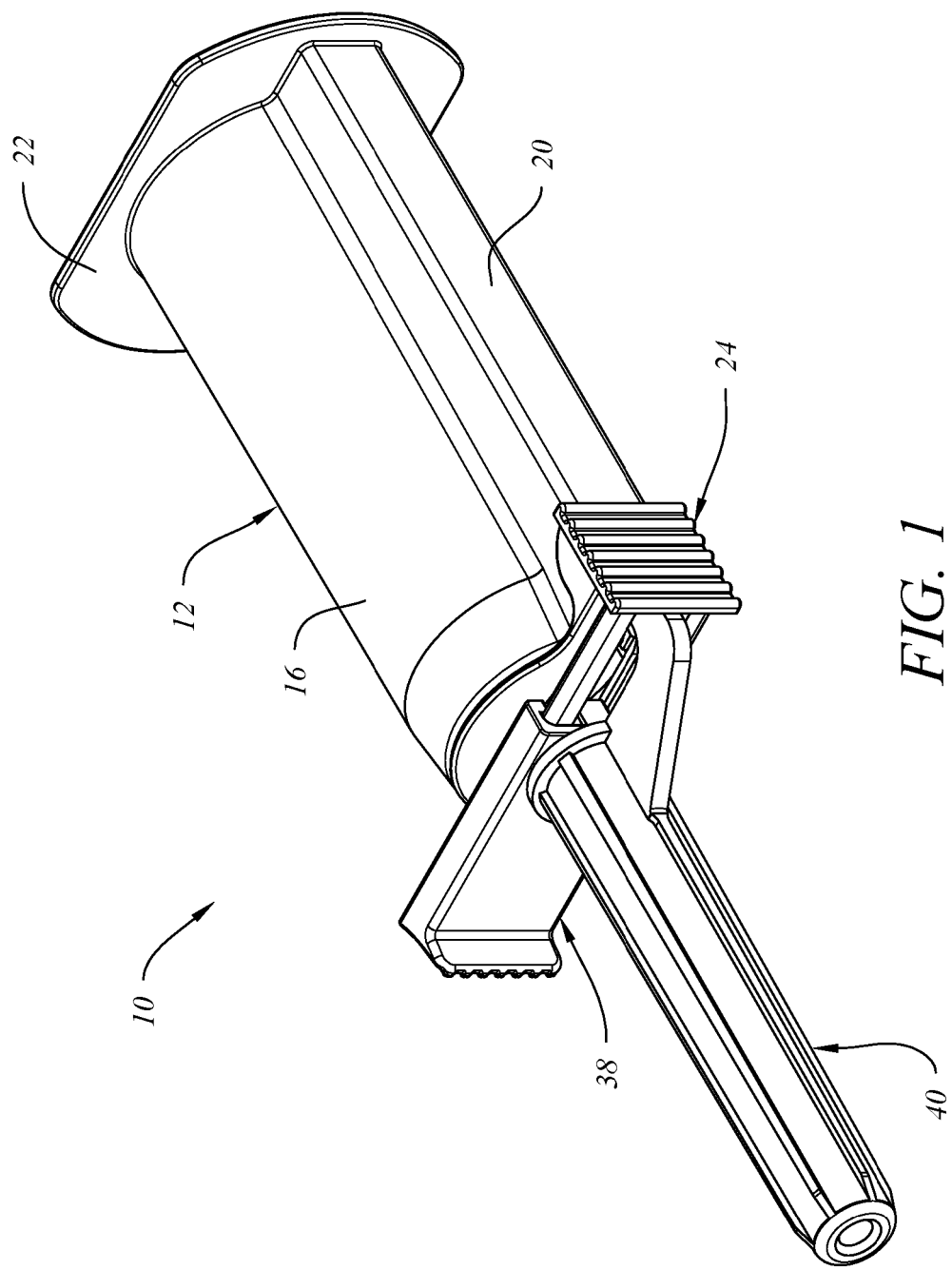


FIG. 1

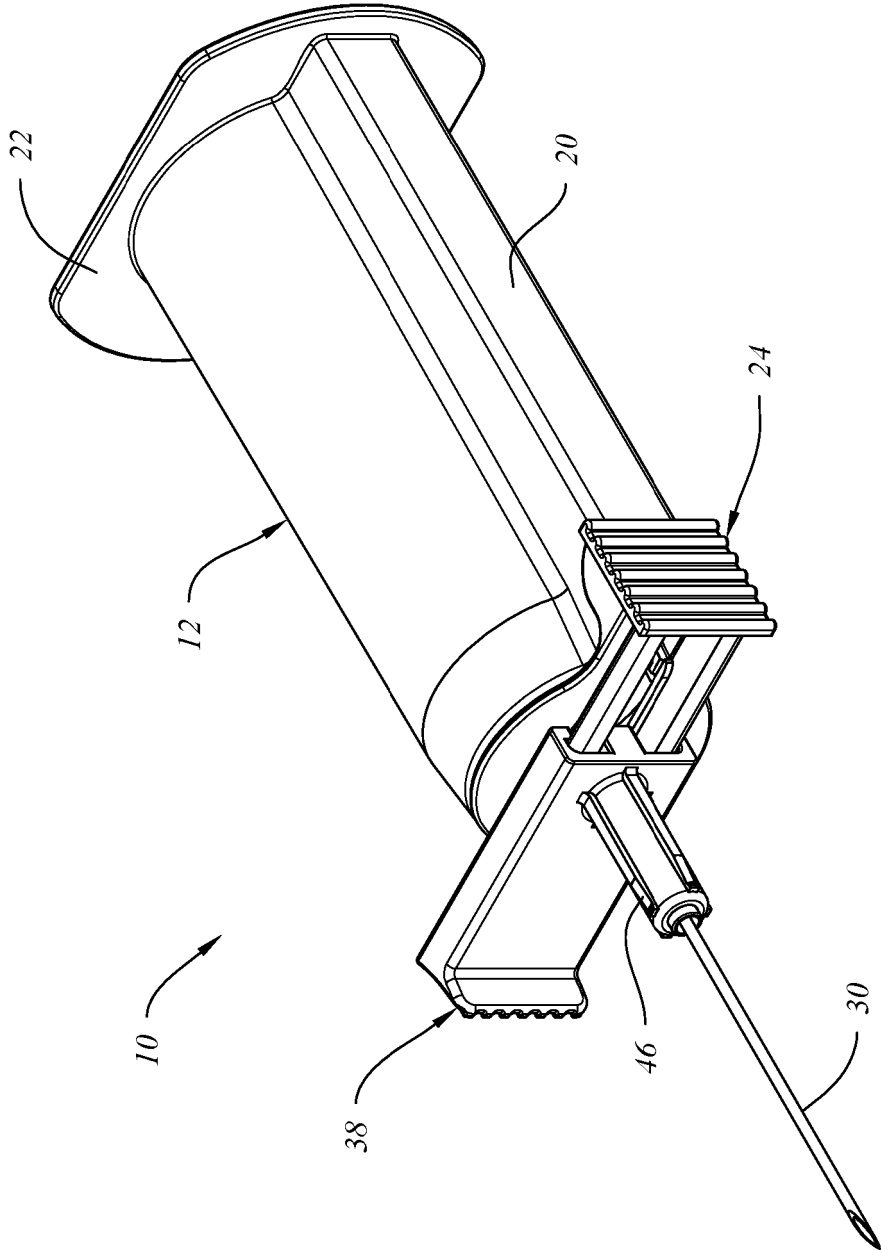


FIG. 2

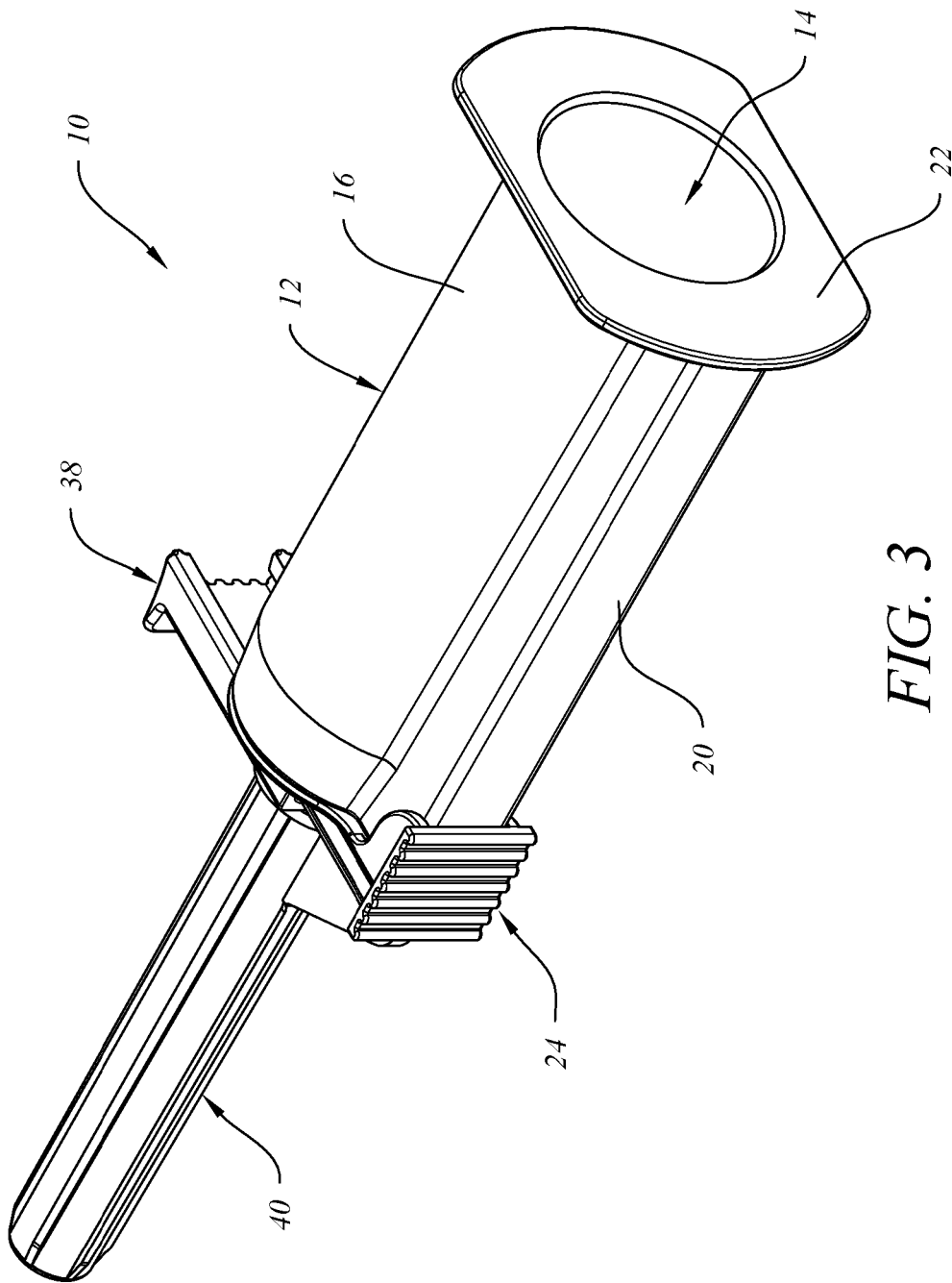


FIG. 3

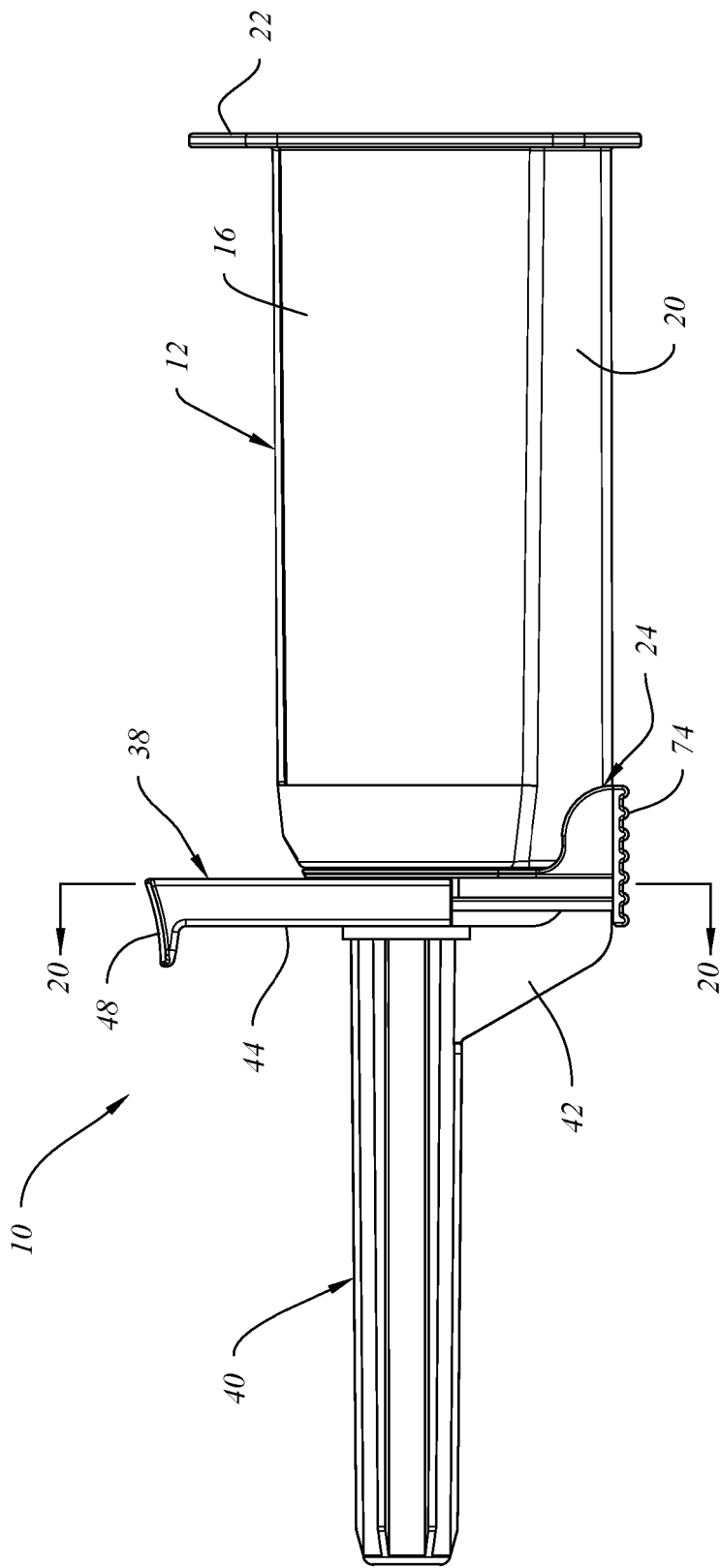


FIG. 4

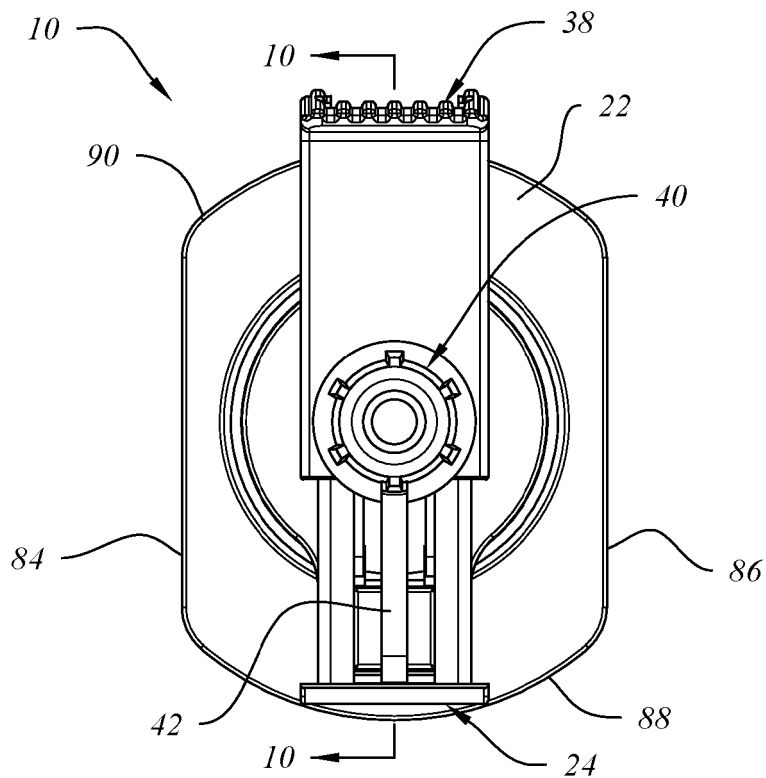


FIG. 5

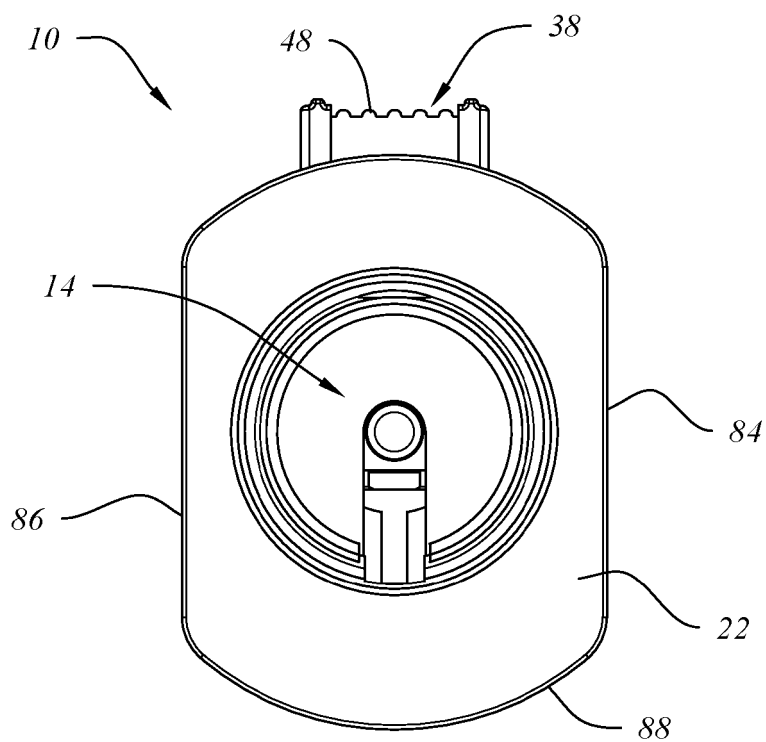
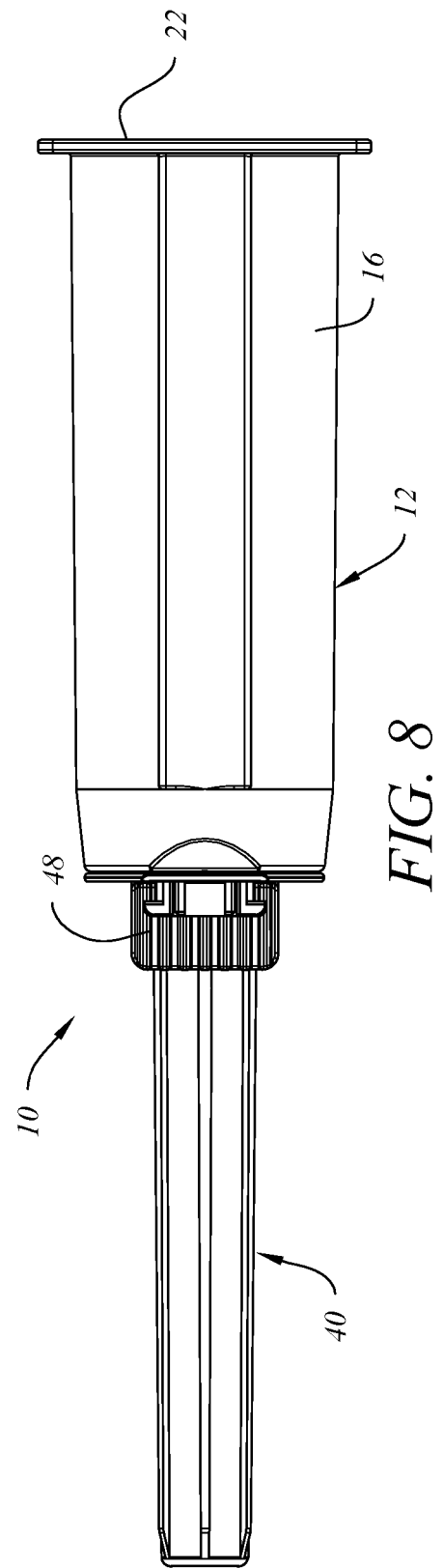
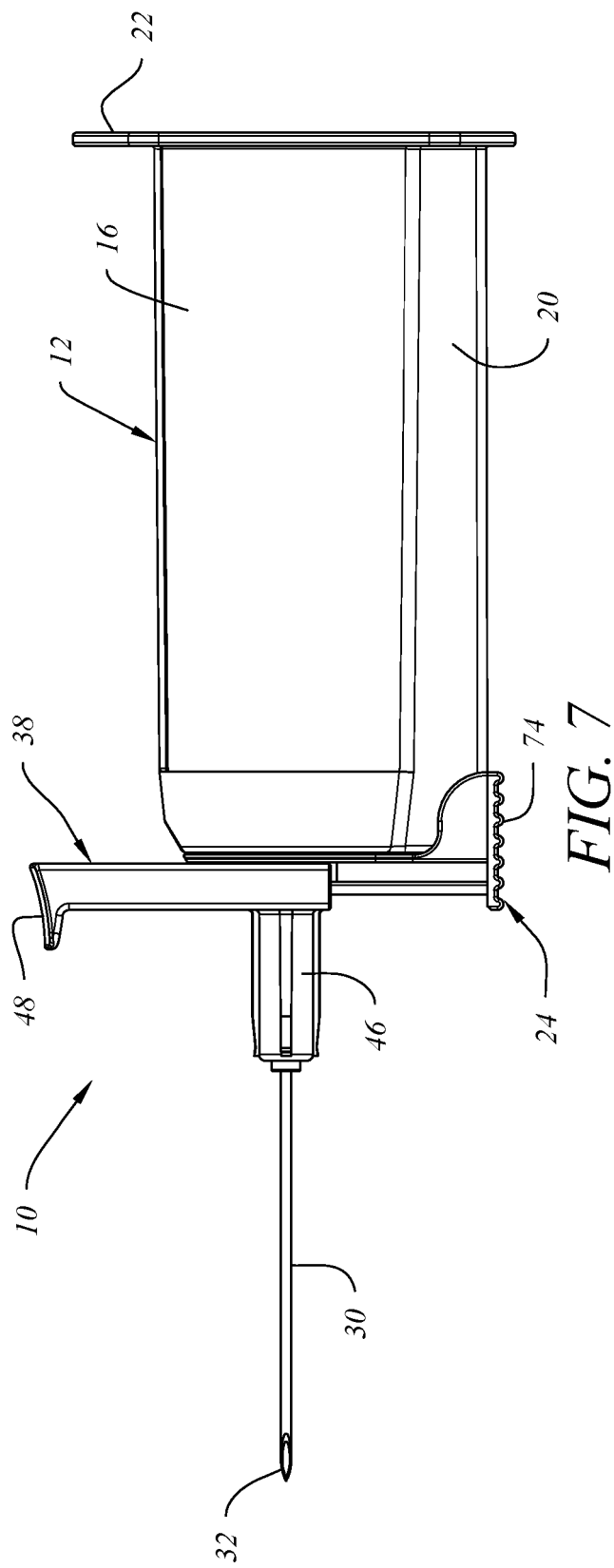


FIG. 6



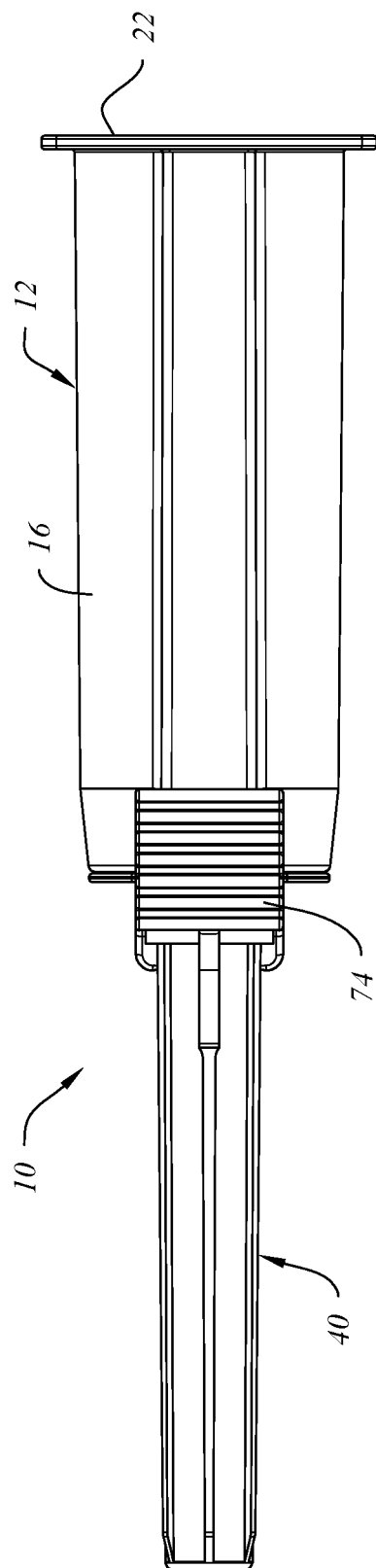


FIG. 9

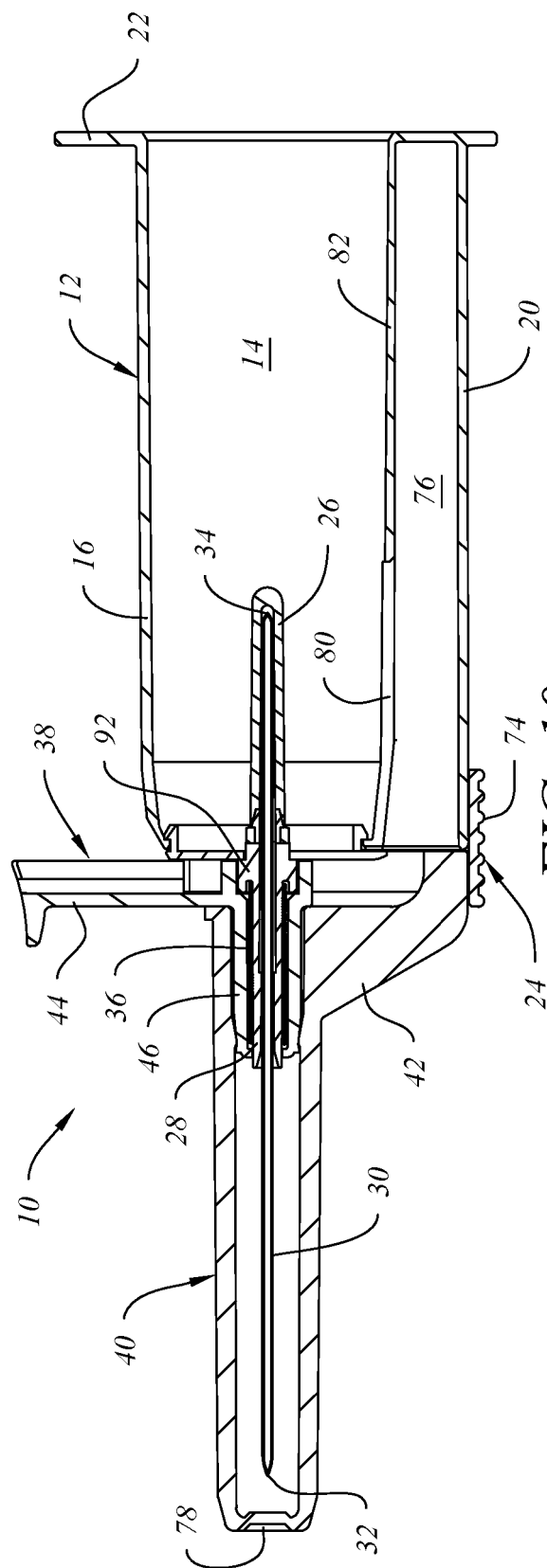


FIG. 10

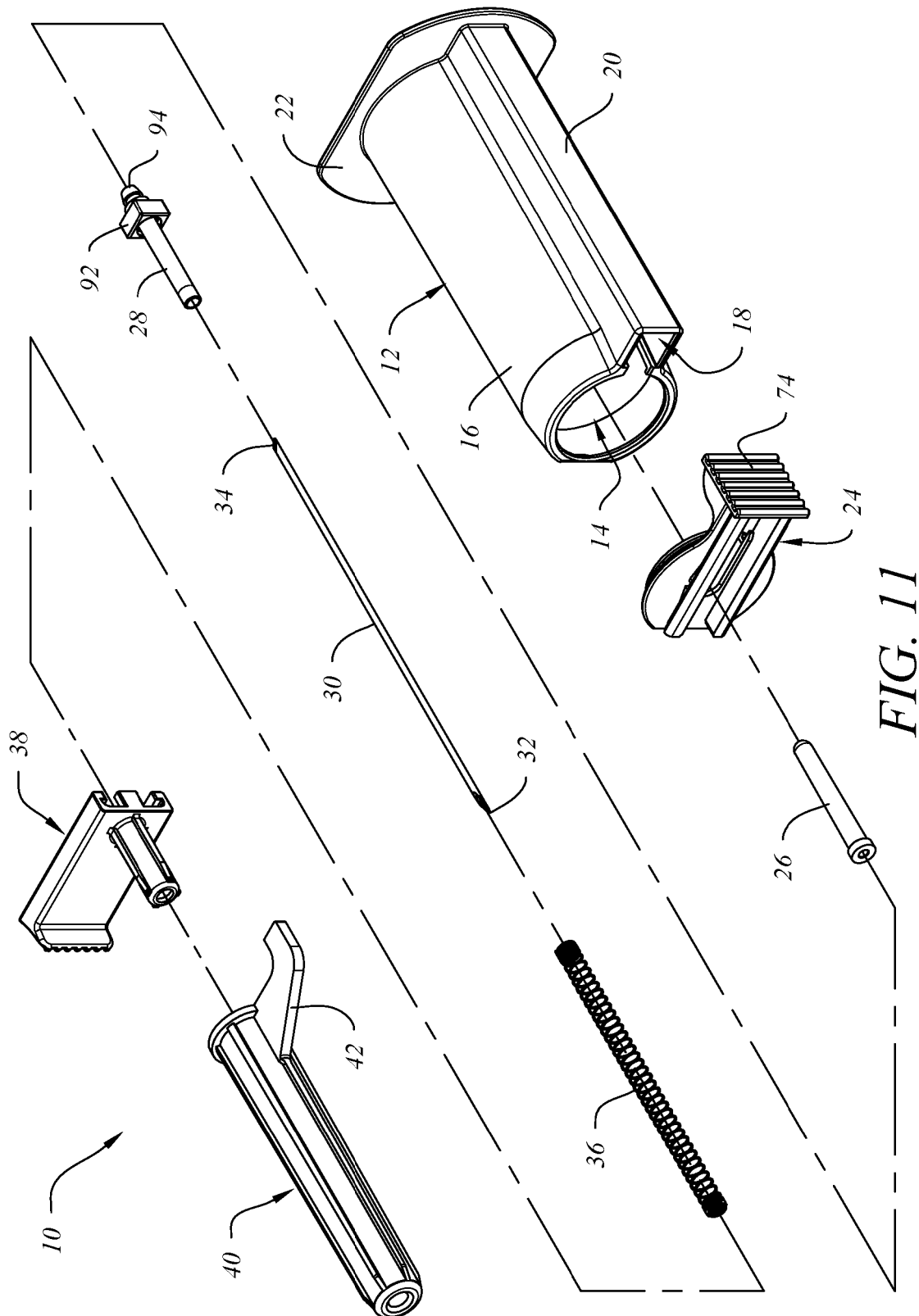
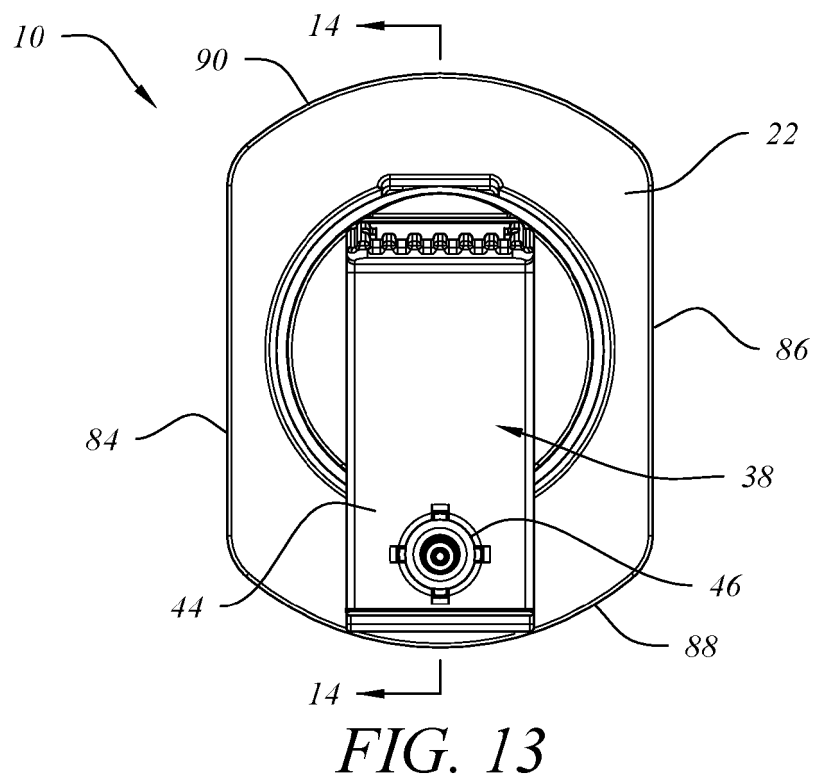
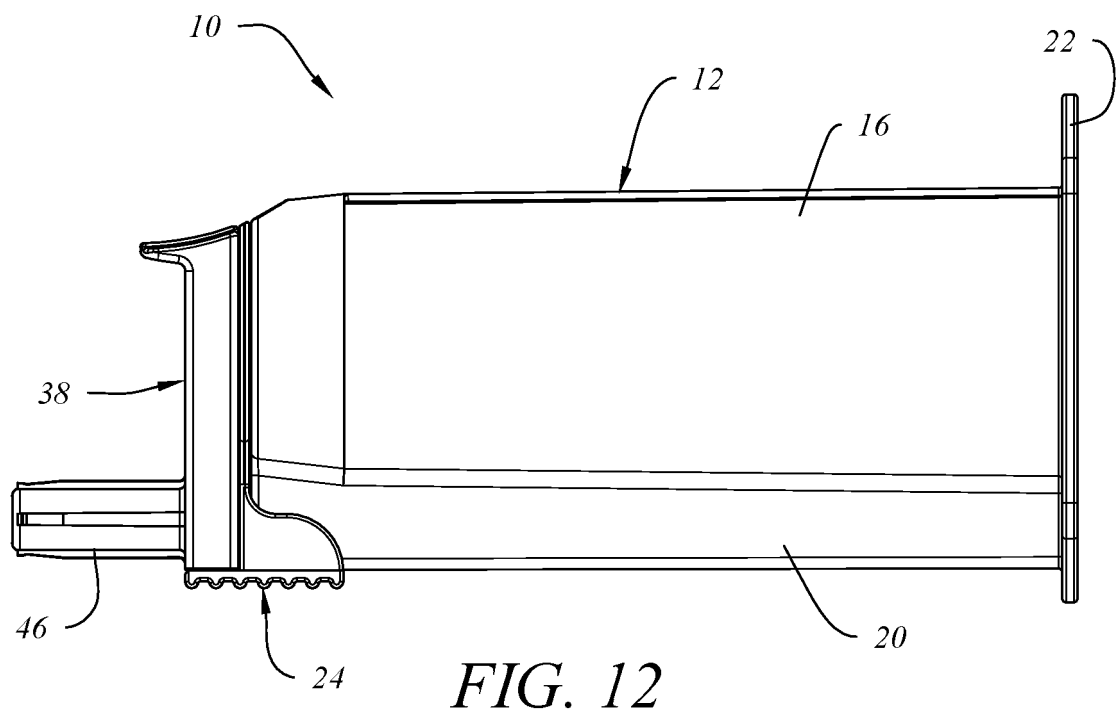
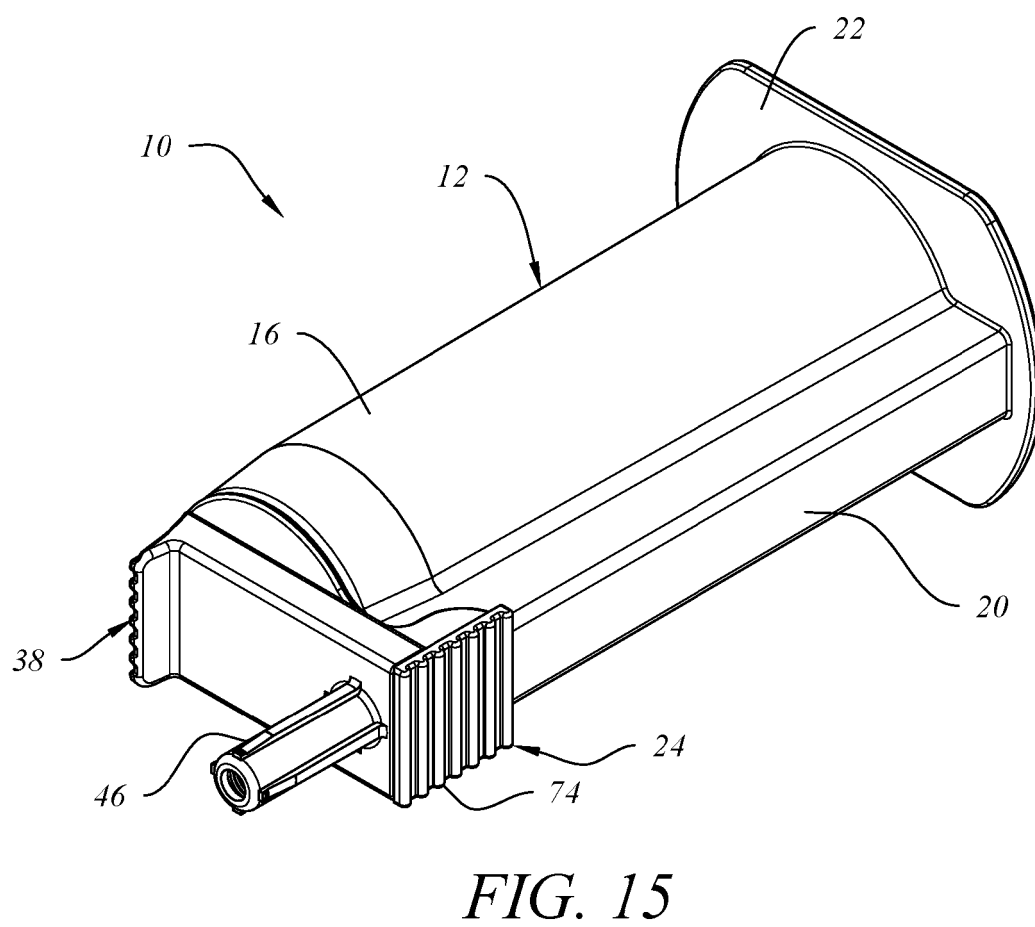
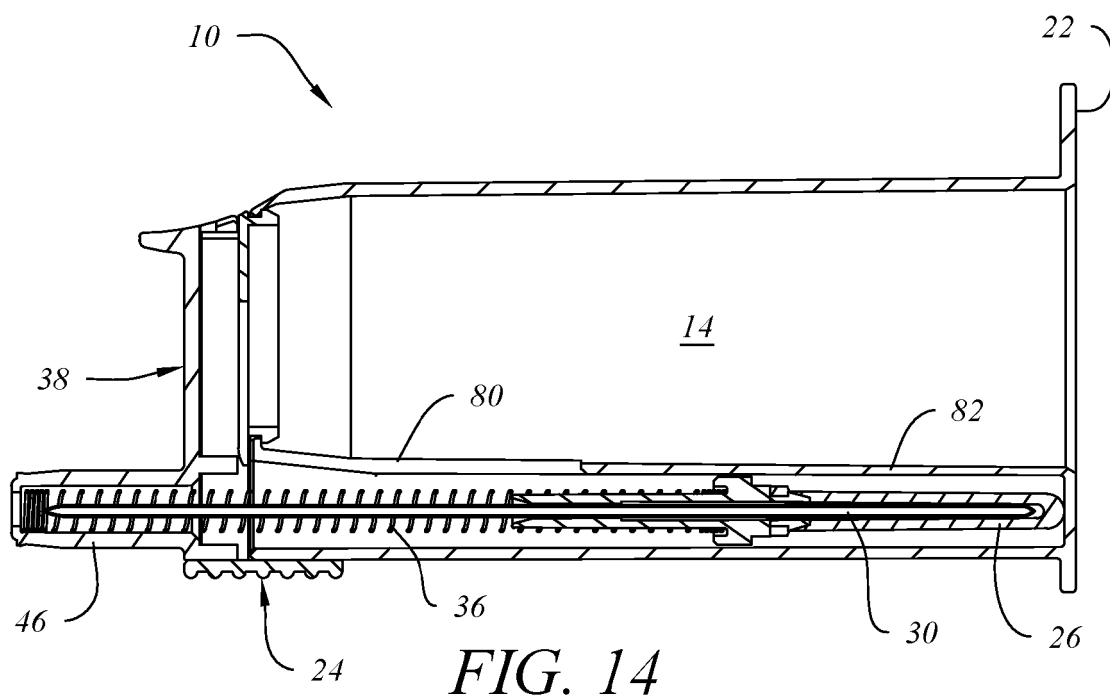


FIG. 11





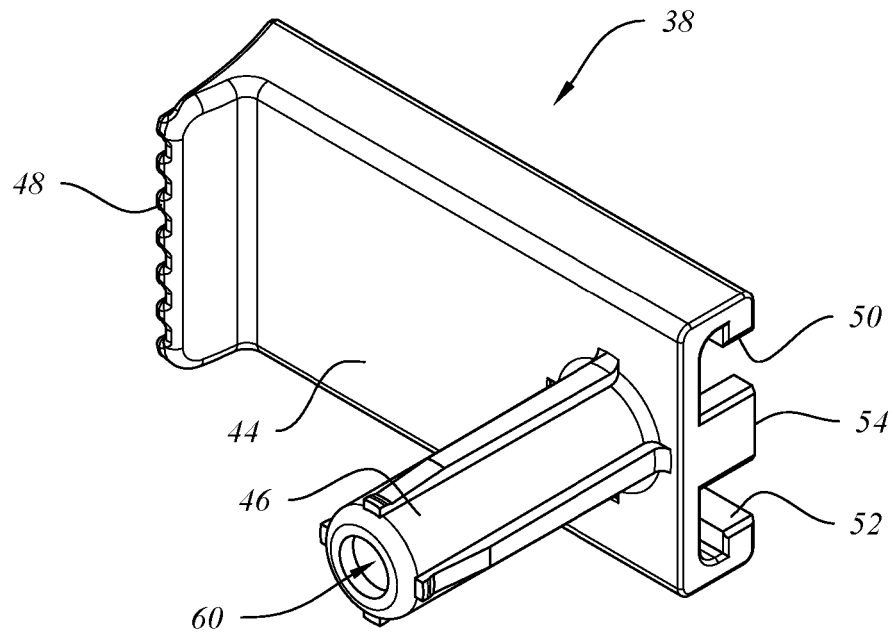


FIG. 16

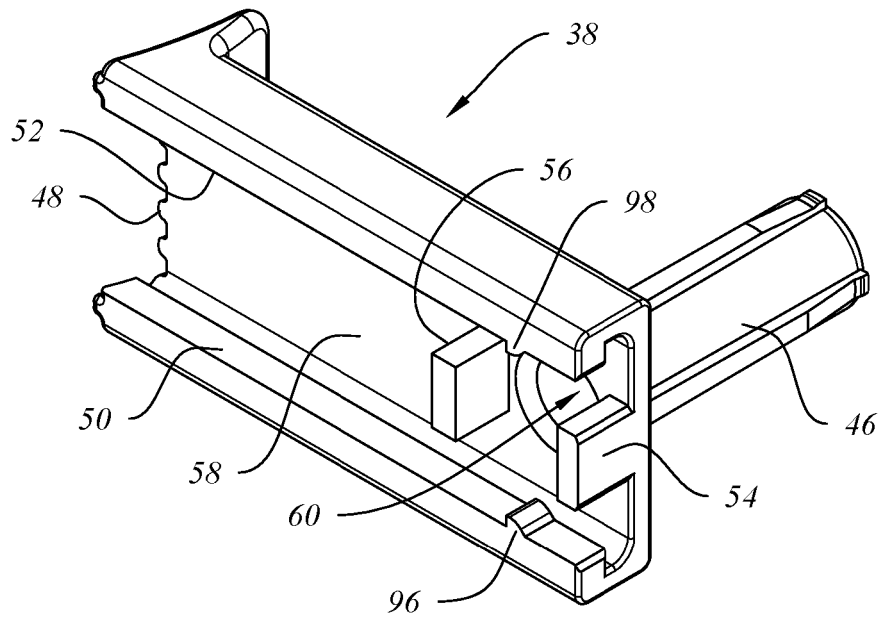


FIG. 17

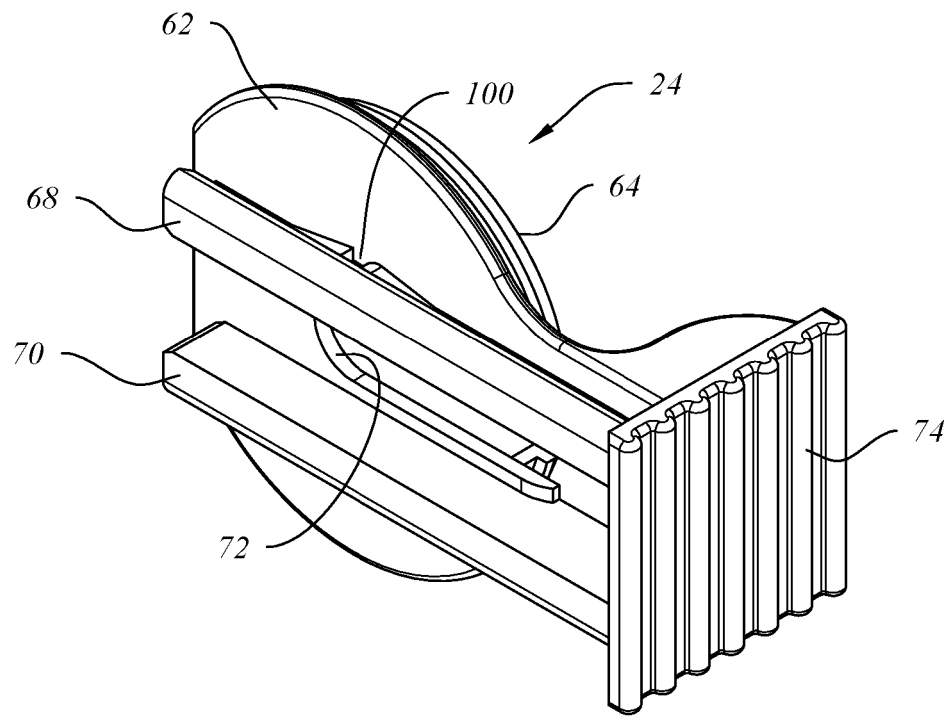


FIG. 18

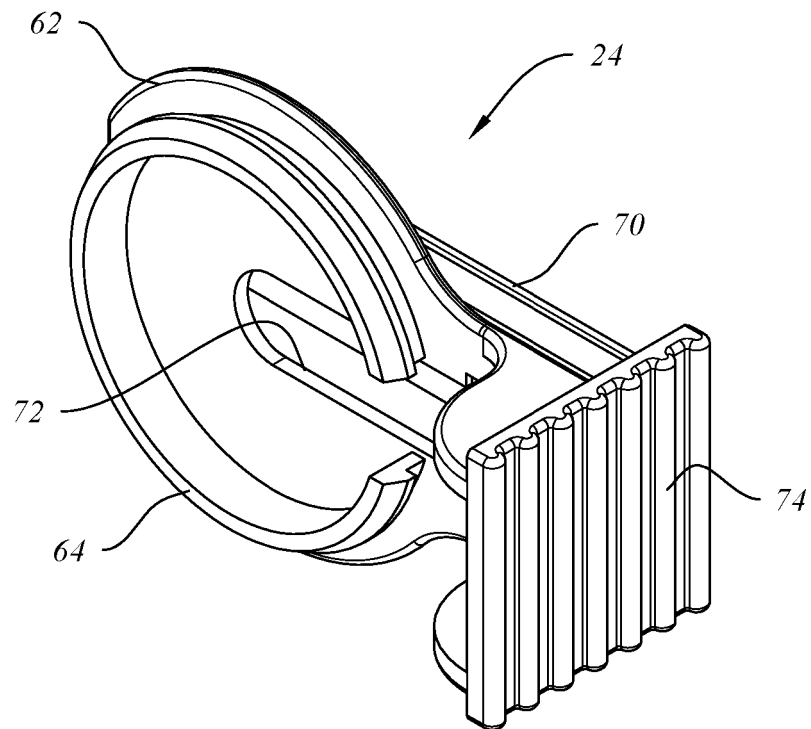
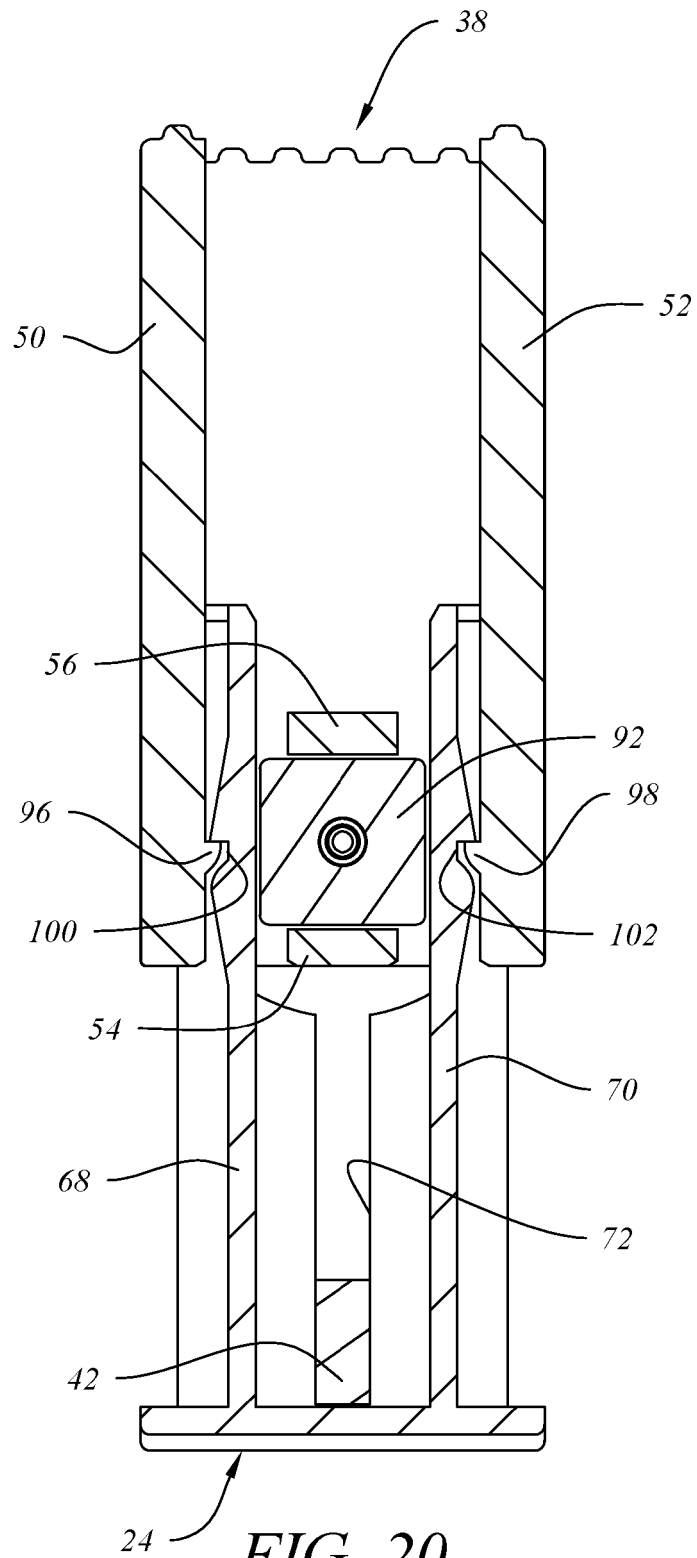


FIG. 19



REFERENCES CITED IN THE DESCRIPTION

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